U.S. Department
of Transportation
**Research and
Special Programs
Administration**

400 Seventh St., S.W.
Washington, D.C. 20590

MAR 19 2001

Reference No.: 00-0345

Mr. Ken Sumner
President
KWS Training, Inc.
P.O. Box 562
Carrboro, NC 27510

Dear Mr. Sumner:

This is in response to your December 6, 2000 letter inquiring whether a device designed to administer medicine through human skin without using a needle would be considered an "Aerosol" under the Hazardous Materials Regulations (HMR; 49 CFR Parts 171-180) or under the ICAO Technical Instructions.

You state that the device consists of two separate chambers. The gas chamber is made of metal, filled with nitrogen gas (water capacity 0.6 mL) to a pressure of 293 bar (~4,248 psi) at 100 °C. The other chamber for the medicine is less than 5 mL. When the device is activated, the chamber pressure drives a ram mechanism, which moves a piston in the medicine chamber and propels the liquid medicine through the skin.

The answer is no. The device that you describe does not meet the definition of an "Aerosol" in § 171.8 in the HMR or US variation 6 in the ICAO Technical Instructions. However, the device may be transported under the "Limited quantity" provisions in 173.306(a)(1) as "Nitrogen, compressed, 2.2, UN1066.

I hope this satisfies your request. Please contact us if we can be of further assistance.

Sincerely,

Hattie L. Mitchell

Hattie L. Mitchell
Chief, Regulatory Review and Reinvention
Office of Hazardous Materials Standards

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171.8
Definition
Applicability
00-0345

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12/6/00

Mr. Edward T. Mazzullo
Director, Office of Hazardous Materials Standards
U.S. DOT/RSPA (DHM-10)
400 7th Street S.W.
Washington, D.C. 20590-0001

Dear Mr. Mazzullo,

This letter is to request your opinion on whether a device may meet the definition of aerosol under 49 CFR and by reference in 49 CFR 171.11, the ICAO Technical Instructions, even though the device does not operate like a typical aerosol.

The device is designed to administer a dose of medicine through human skin without using a needle. A blast of pressure comes from a small (water capacity 0.6ml) metal chamber of nitrogen gas. The chamber is filled to a pressure of 293 bar (~4,248 psi) at 100° C.

The propellant and the medicine are in separate chambers of the device and do not come into contact with one another, even on actuation of the device. When the device is activated the chamber pressure drives a ram mechanism, which moves a piston in the medicine chamber and propels the liquid medicine through the skin. The device is designed for single-use, with no residual pressure remaining after activation.

According to 49 CFR 171.8 an aerosol is "...any non-refillable metal receptacle containing a gas compressed, liquefied or dissolved under pressure, the sole purpose of which is to expel a nonpoisonous (other than a Division 6.1, Packing Group III material) liquid, paste or powder and fitted with a self-closing release device allowing the contents to be ejected by the gas."

According to the ICAO Technical Instructions (Part 2 Chapter 2 2.5.1) an aerosol is "...any non-refillable receptacle made of metal, glass or plastic and containing a gas compressed, liquefied or dissolved under pressure, with or without a liquid, paste or powder,

and fitted with a self-closing release device allowing the contents to be ejected as a solid or powder, or in a liquid or gaseous state."

This device is non-refillable, and contains a compressed gas intended to expel a medicine. The gas chamber is made of metal, while other components of the device are metal, plastic and glass. The device has a latch mechanism, a seal, and stopper to prevent accidental release. Once activated no pressure will remain, making a self-closing device unnecessary.

The primary concern is that although the device is one unit, the gas and medicine are in two separate containers--the gas is in a metal chamber and the medicine is in a separate glass container within a plastic sleeve.

Your response to the following questions will be greatly appreciated:

1. Is it necessary for the gas chamber and the container of medicine to be in the same chamber to meet the definition of aerosol?
2. Is a self-closing mechanism required if the device is single-use, with no residual pressure after activation?
3. Can an aerosol "expel" its contents by mechanical means, without being in direct contact with the propellant?
4. Does this device meet the definition of "aerosol" as contained in 49CFR and ICAO regulations?

regards,

Ken Sumner
President